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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,798	10/21/2003	Jay Edelberg	1676.001US2	5627

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EXAMINER	
MALLARI, PATRICIA C	
ART UNIT	**PAPER NUMBER**
3735	

MAIL DATE	DELIVERY MODE
05/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,798	EDELBERG ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *59-78 and 80-106* is/are pending in the application.

4a) Of the above claim(s) *59-73,77 and 85-106* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *74-76,78,80-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 October 2003 and 09 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/2/07 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 80-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 80 recites "The biosensor according to claim 79" which has been cancelled. It is not apparent from the claim language alone from which of the pending claims claim 80 should depend. For the purpose of this examination only, the examiner is treating claim 80 as if it were dependent upon claim 74. In any case, the applicants must correct the claim dependency in claim 80. Further, claim 80 recites "the animal". There is insufficient antecedent basis for this limitation in the claim, and since there is no reference to an "animal" in any of the other claims, it is further unclear as to how or if

"the animal" relates to the claimed biosensor. For the purpose of this examination only, and because claim 74 contains reference to a "mammalian subject", which is a type of animal, the examiner assumes the "animal" refers to the "mammalian subject" on line 4 of claim 74. In any case, the applicants must amend the language of claim 80 to clarify the relationship of "the animal", if any, to the claimed invention.

Claims 81 and 82 depend from claim 80, and, therefore, also suffer from the same deficiencies, set forth above, as claim 80.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> Or
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 74, 76-78, and 80-83 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,368,028 to Palti. Palti teaches an implantable physiological or pathophysiological biosensor comprising cells (see entire document, especially col. 9, lines 16-31 of Palti) coupled to an electrical interface (see entire

document, especially col. 6, lines 14-19; col. 11, lines 4-25 of Palti) and adapted to be electrically coupled to endogenous tissue or cells when implanted into a mammalian subject at a site distant from a natural site for a physiological or pathophysiological function of the subject (see entire document, especially col. 6, line 66-col. 7, line 9; col. 11, line 44-col. 12, line 26 pf Palti). The cells are adapted to electrically couple with endogenous tissue or cells via the transmission means, such as the transmitter that sends the processed signals through the skin, the implanted electrodes and amplifier for generating an electric field, or an induction coil or coupling capacitive signal transferor. The cells are capable of monitoring a chemical, physiological, or pathophysiological variable associated with the physiological or pathophysiological function of the subject (see entire document, especially col. 9, line 16-col. 10, line 34 of Palti) and are further capable of producing at least a hormone, wherein beta cells from the islets of Langerhans, for example, are capable of producing insulin, which is a hormone.

As to the language "in vitro or ex vivo modified stem cells", the applicant should note that this is "product-by-process" language, wherein the structure implied by the process steps, rather than the process itself, is given patentable weight. See MPEP 2113. In the case of "in vitro or ex vivo modified stem cells", the structure implied by the process of modifying stem cells either in vitro or ex vivo are merely other cells. For example, beta cells may be produced by modifying stem cells in vitro or ex vivo. Claim 76 contains more language regarding the process by which the cells are produced, wherein the process language again implies no more than another cell, such as a beta cell, which may be produced by cellular engineering.

Regarding claim 77, beta cells, for example, are capable of producing vascular endothelial growth factor (VEGF).

Regarding claim 78, the physiological or pathophysiological variable is a level or activity of at least blood glucose (see entire document, especially col. 9, lines 25-55 of Palti).

Regarding claims 80-82, the biosensor clearly appears capable of being implanted into any mammal. The language "when implanted into a mammalian subject" is "intended use" language which cannot be relied upon to define over the prior art, since Palti teaches all of the claimed structural features and their recited relationships. Ex parte Masham 2 USPQ2d 1647 (BPAI 1987).

Regarding claim 83, the cells are incorporated within a device (see entire document, especially col. 10, line 41-col. 12, line 61 of Palti).

Claims 74-76 and 80-84 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application Publication No. 2003/0211088 to Field. Field teaches an implantable device comprising in vitro or ex vivo modified stem cells coupled to an electrical interface 12 and adapted to be electrically coupled to endogenous tissue or cells when implanted into a mammalian subject at a site distant from a natural site for a physiological or pathophysiological function of the subject (see entire document, especially fig. 1; paragraphs 13, 18, 23-25, 40-42, and 62 of Field). The cells (cardiomyocytes) can monitor a chemical, physiological, or pathophysiological variable associated with the physiological or pathophysiological function of the subject, wherein

the applicants' specification identifies cardiac cells/cardiomyocytes as capable of such monitoring (see p. 9, line 25-p.10, line 9; p.11, lines 4-6; p. 22, line 25-p.23, line 15 of the instant specification, for example), and cardiomyocytes can produce at least a growth factor, such as a vascular endothelial growth factor.

As to the language "when implanted into a mammalian subject at a site distant from a natural site for a physiological or pathophysiological function of the subject", the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art, since Field teaches all of the claimed structural limitations and their recited relationships. Ex parte Masham 2 USPQ2d 1647 (BPAI 1987). The device of Field is certainly capable of implantation at any site in a mammalian subject in which size permits, wherein the site may clearly be distant from a natural site for a physiological or pathophysiological function of the subject.

The examiner notes the use of the term "biosensor" in the preamble of claim 74. However, the term fails to denote any structural features not already present in the device of Field. Furthermore, Field teaches all of the structural features claimed in the body of claim 74 and their recited relationships as set forth above. If the device of Field lacks a structural feature necessary for its function as a "biosensor", then it would appear that the applicants have failed to include an essential element of the invention.

Regarding claim 75, cardiomyocytes are capable of producing vascular endothelial growth factor (VEGF).

Regarding claim 76, the cells are genetically engineered (see entire document, especially paragraphs 23-28 of Field).

Regarding claims 80-82, the device is capable of being implanted in any mammal.

Regarding claims 83 and 84, the cells are incorporated within a device such as an electronic pacemaker (see entire document, especially fig. 1; paragraphs 40, 41, and 62 of Field).

Response to Arguments

Applicant's arguments with respect to claims 74-76 and 78-84 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia Mallari/
Patricia Mallari
Patent Examiner
Art Unit 3735